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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/771,961
Filing Date: January 29, 2001
Appellant(s): TURNER ET AL.

Lance K. Ishimoto
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 29 August 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the real party in interest is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is essentially correct, except that the asserted utilities for the claimed invention are currently being disputed.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-8 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

Sklonick et al. Structural genomics and its importance for gene function analysis, Nature Biotechnology. Vol. 1 8, NO:3, March 2000, pages 283-287.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial and credible asserted utility or a well established utility.

Claims 1-8 are drawn to the nucleic acid molecules comprising the nucleic acid sequence of SEQ ID NO: 1 or nucleic acids encoding the protein of SEQ ID NO: 2, or an isolated nucleic acid that hybridizes under specific recited conditions to the nucleotide sequence of SEQ ID NO:1 or complement thereof, or nucleic acids encoding the protein of SEQ IDNO:4. The instant specification identifies the proteins of the instant invention as novel human proteins (NHPs) and discloses that the full length of the polypeptide of SEQ ID NO:2 is 248 amino acids. The instant specification discloses that the protein of the instant invention has structural similarity with membrane receptors such as, but not limited to mammalian CD82 and CD37, (page 1, lines 25-31). The instant specification also discloses that the NHP encoded by the claimed nucleic acid displays four transmembrane regions as have been seen in similar proteins, (see page 15, lines 10- 16). However, the instant specification does not disclose any information regarding physiologic or functional characteristics of the NHPS of the instant invention, encoded by the claimed nucleic acid molecule, therefore, the NHP nucleic acid molecules or encoded proteins do not have any specific and substantial utility, or a well established utility, as determined according to the MPEP §2107.

The instant application describes the uses and methods of the invention, and state that the nucleic acids and proteins can be used in methods such as screening assays to identify receptors, binding proteins, agonists or antagonists which may

potentially be drugs, making transgenic animals to also use in screening assays, use of the protein to raise antibodies, use of the nucleic acids to identify mutant alleles, expressing the nucleic acid in order to make the protein, or as probes to screen for libraries and isolate clones, or assess gene expression patterns, for example.

However, none of these uses are considered to be specific or substantial utilities for either the nucleic acid molecules or the protein encoded by them. Methods such as identification of receptors, agonists or antagonists, screening for homologous genes, use to identify polymorphisms or alleles, use to recombinantly produce protein or use to generate antibodies are considered general methods applicable to any nucleic acid and/or protein, and are not considered specific.

The instant application also teaches that the nucleic acids have utility in defining and monitoring drug action and toxicity, and to identify mutations associated with certain diseases and disorders. The instant specification also asserts that NHP products such as , antisense nucleic acids, protein and associated antibodies, agonists, antagonists can be used either diagnostically to identify mutations or therapeutically to identify and treat diseases or disorders. However, the assertion that the nucleic acids/and or proteins of the instant invention can be used in diagnosis or treatment of diseases or disorders is also not a specific and substantial utility, and is based on the assumption that the protein is a CD membrane like protein, similar to CD82 and CD37 which are involved in cell-cell interaction and signal transduction. However, belonging the CD membrane family of proteins, does not assure that there is a common biological role for all the members of this family. For instance, is the protein encoded by the claimed

nucleic acid a receptor, and if so what are the cognate ligands that bind it? What signal transduciton pathways does it participate? And what specific diseases is it associated with?

Though sequence homologies may provide information as to the family protein may belong to, they still do not necessarily predict a function. Furthermore, there is no nexus between any diseases or disorders and the molecules of the instant invention. Given no disease state or any other function or activity known for the proteins, the proteins are not considered to have utility. In Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), a process of producing a novel compound that was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be useful because the compound produced thereby was potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. Clearly, further research would be required to identify a disease that is associated with the claimed molecules or a "real world" use. See Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct,.1966), noting that a "patent is not a hunting liscense. It is not a reward for the search, but compensation for its successful conclusion." The instant claims are drawn to a polynucleotide encoding a protein which has undetermined function or biological significance, and the use of a protein to

discover its receptor or properties does not constitute a specific, substantial utility. All of the biological activities of a protein need not be known to obtain a patent, but there must be some specific and substantial activity or function known. It is possible that after further characterization, this protein might be found to have a patentable utility, in which case the polynucleotides encoding the protein would have a specific utility, or the polynucleotides might be found to be associated with a specific disease. This further characterization, however, is part of the act of invention, and until it has been undertaken the Appellants' claimed invention is incomplete.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(11) Response to Argument

A. Do claims 1-8 lack a Patentable Utility?

Initially, it is acknowledged that the instantly claimed polypeptides are similar to CD proteins, rather than BCL-X like protein. The CRF (computer readable form for sequences) submitted by Appellants on 16 April 2002 did not match the paper copy. However, the Appellants filed the correct CRF on March 12, 2004, and once the correct

sequences have been searched, it is apparent that the sequences of the instant invention are not like BCL-X protein. Thus, Applicants' assertion that the claimed polypeptides share some similarity to CD proteins is accepted, because the protein of SEQ ID NO: 2 of the instant invention shares 15.3% identity to human CD63 and 24.3% to human CD82. (See attached copies of the comparison of SEQ ID NO:2 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A' and "B").

Beginning at bottom of page 5 of the Brief, Appellants submit results of a BLASTP analysis comparing SEQ ID NO:2 and International Protein index data base and point out that it has been annotated by third party scientists wholly unaffiliated with Appellants as human protein similar to CD63 antigen, (GenBank accession number: XP 084868, alignment and GeneBank report provided in Exhibit B, (also shown in Exhibit C and D), shares 100% identity from amino acid residue 216 to amino acid residue 248 of SEQ ID NO: 2 of the instant invention. applicants further point out that the annotation to this entry has changed from being similar to CD82 antigen to being similar to CD63 antigen. Appellants maintain that their position that the polypeptide of the instant invention is a CD-like protein is still valid since both CD82 and CD63 would be recognized as CD like proteins by those skilled in the art. Appellants argue that given this clear and convincing evidence that those skilled in the art have independently identified the sequences of the present invention as encoding a protein similar to CD like membrane protein similar to CD82 and CD63, there can be no question that Appellants' asserted utility for the described sequences is "credible", and as such, the scientific evidence of identity at both the amino acid and nucleic acid levels clearly

establishes that those of skill in the art would recognize that sequences of the present invention as a human CD-like, and has all the recognized utility, and therefore Appellants have described a utility in full compliance with the provisions of 35 U.S.C. ' 101.

Appellant's arguments have been fully considered but are not deemed to be persuasive for the following reasons. First, while the protein of SEQ ID NO: 2 of the instant invention may be 100% identical to a protein identified in the art as CD63- like protein, the protein of SEQ ID NO: 2 of the instant invention is only 15.3% identical to human CD63 itself and 24.3% to human CD82; and it is therefore divergent from these proteins 84.7% and 74.7%, respectively. It is credible that the proteins of the instant invention are indeed similar to CD63 and are probably in the CD membrane family, but given the high level of amino acid divergence, do not necessarily bind the same ligands as CD63 or have the same activities. Second, the CD-membrane family of proteins have very diverse functions, as discussed below. Therefore, similarity to CD proteins does not necessarily lend a specific and substantial utility and the credibility of the similarity is not questioned.

On top of page 7 of the brief, Appellants assert that the Advisory Action mailed 15 July 2003 discounts the Appellants' position that utility can be distinct from physiological function. Appellants submit that many enzymes are used in commercial processes, a clear utility that is distinct from their physiological role. On the same page, Appellants assert that the Examiner seems to be requiring Appellants to identify the biological role of the nucleic acid or function of the protein encoded by the presently

claimed polynucleotides before the present sequences can be used in gene chip applications that meet the requirements of 35. U.S.C. § 101, and that knowledge of the exact role of function of the presently claimed sequences are not required for the claimed nucleic acids to track expression patterns using a gene chip. Appellants reiterate the arguments presented in the response filed on 05 May 2003 by pointing out that the claimed sequences would have great utility in such gene DNA chip applications, and that the claimed sequences provide a specific marker of the human genome, and that such specific markers are targets for discovering drugs that are associated with human disease. Appellants further assert that additional evidence of the "real world" substantial utility of the present invention is further provided by the fact that there is an entire industry based on the use of gene sequences or fragments thereof in a gene chip format, and cite a number of companies that have concentrated on the use of gene sequences or fragments, in gene chip and non-gene chip formats, and that the "real world" substantial industrial utility of gene sequences or fragments would, therefore appear to be widespread and well established, and have both scientific and commercial utility. Thus, Appellants contend that that compositions that enhance the utility of such DNA gene chips, must in themselves be useful.

This argument has been considered fully, but is not deemed persuasive for the following reasons: first it is correct that enzymes as a class are used in commercial processes, however, each enzyme must perform a specific function, and therefore, must have a specific and substantial utility. The skilled artisan must know how to use each enzyme. Novel enzymes must demonstrate a specific role, in order to satisfy the

requirements under 35 U.S.C.§ 101. Second, Appellants mischaracterize the Examiner's position as requiring Appellants to identify the biological role of the nucleic acid or function of the protein encoded by the presently claimed nucleic acid before the present sequences can be used in gene chip applications. The biological role of a polynucleotide or encoded protein is not required to render a gene chip useful, and it is not disputed that gene chip technology is a well established utility currently being exploited by a number of companies to determine correlations between expression patterns of nucleic acids and diseases. The Examiner would like to draw the Board's attention to the definition of the terms "a gene chip" mentioned in the Brief and in the instant specification by the Appellant. A gene chip is a customized device in biomedicine that allows researchers to detect, simultaneously, the presence and activity patterns of tens of thousands of DNA sequences. A gene chip can be used by researchers to describe the genetic malfunction associated with a disease, detect the presence of the disease in a particular patient, calculate a patient's genetic predisposition to that disease or identify the medicines likely to be most effective in treating a particular patient with the disease. A correlation is required between altered expression of a nucleic acid and a particular disease or disorder; otherwise experimentation is required to determine what genes are altered in which diseases. The point is that while a set of nucleic acids in a chip may have utility as a group, a single member of that group does not necessarily have a specific and substantial utility. If the claimed compound is only useful as part of a larger mixture of compounds, then it is the mixture, and not the individual compounds, which have utility.

Appellants' argument on pages 7-8 of the brief that as only a small percentage of the genome actually encodes exons, which in turn encode amino acid sequences, not all human cDNA sequences are useful in such gene chip applications, and that this further discounts the Examiner's position the such uses are "generic" has been fully considered, but not deemed persuasive, because as discussed above, the Examiner acknowledges that gene chip technology has utility. However, the utility of gene chips is the combination of sequences, and not a single sequence, and if as asserted any nucleic acid encoding a protein has utility because it would enhance the utility of a DNA gene chip, this is not a specific and substantial utility for any single nucleic acid sequence present in the chip.

On page 9 of the brief Appellants point out that the basis for DNA chip analysis is the differential expression of specific sequences, which may or may not represent a particular gene, are examined for differential expression in normal and diseased tissues. Thus, Appellants assert that the sequences of the present invention which represent a specific gene that encodes a membrane protein similar to CD63 which is expressed in certain tissues and not others has a particular value in such forms of analysis. Appellants' arguments have been fully considered but are not deemed persuasive for the following reasons. The instant specification and brief assert that the nucleic acids of the instant invention are specifically expressed in certain tissues, such as human trachea, prostate, uterus, mammary gland, salivary gland, etc; while not expressed in other tissues. However, Appellants have not established that the claimed nucleic acid sequences or the encoded proteins are expressed at altered levels or forms in a specific

diseased tissue as compared with the corresponding healthy tissue. If the claimed nucleic acid molecules were in a gene chip and a compound caused decreased expression of the claimed nucleic acids, what would that mean to the skilled artisan? Is it a potential drug, or would administering the compound be likely to acerbate an unspecified disease? If it had been disclosed that the claimed nucleic acids are expressed at a higher level in a particular diseased tissue as compared with the corresponding healthy tissue, then the skilled artisan would infer that a compound that decreased expression of the nucleic acid molecule might be a good drug candidate that targets the disease. However, such would still require substantial further experimentation and it is not the case here. In addition, the claimed nucleic acid molecules may very well be expressed at equivalent levels in healthy tissues. If that were the case, then the compound would not be a good drug candidate. The claimed nucleic acid molecules may also very well be expressed at a lower level in a particular diseased tissue as compared to the corresponding healthy tissue. Then a compound that decreased expression of the claimed polynucleotides would not be a good potential drug. Evidence of a differential expression might serve as a basis for use of the claimed nucleic acid molecule as a diagnostic for a disease. However, in the absence of any disclosed relationship between the claimed nucleic acid molecules (or proteins encoded by the nucleic acids) and any diseases or disorders, any information obtained from an expression profile would only serve as the basis for further research on the observation itself. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." Brenner v. Manson,

148 USPQ at 696. Thus, the disclosure does not present a substantial utility that would support the requirement of 35 U.S.C. §101.

There is no doubt that a gene chip (or DNA chips) is a valuable tool in gene expression monitoring and drug discovery. However, the claims are not drawn to the technique, rather to nucleic acid molecules which have not been disclosed as being associated with any particular diseases or conditions by its being expressed at an altered level or form in a specific diseased tissue as compared to the corresponding healthy tissue. Any nucleic acid molecules could be added to a gene chip. The use of the claimed uncharacterized nucleic acid molecules in such studies would have provided no more informative information than the use of any other unidentified nucleic acids. Thus, this asserted utility is not specific. Determining the relationship between the claimed nucleic acid molecules and any specific diseases or disorders would require significant further research. Therefore, this asserted utility is also not substantial.

On pages 9-11of the Brief, Appellant summarizes case law on the utility requirement. Citing case law, Appellant urges that the present claims clearly meet the requirement of 35 U.S.C. '101. The essential disagreement appears to be the interpretation of what constitutes a specific, substantial and credible utility. Appellants' arguments have been fully considered but are not deemed to be persuasive for the following reasons. First, the statement, "(t)o violate '101 the claimed device must be totally incapable of achieving a useful result." Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1571, 24 USPQ2d 1401 (Fed. Cir. 1992), indicates that a rejection under 35 U.S.C. § 101 for lack of operability can be overcome by a showing of

actual use or commercial success. The claimed invention in the instant case is drawn to nucleic acid sequences, not a device; the instant rejection under 35U.S.C. '101 is not directed to inoperativeness of a device, rather to a lack of patentable utility of the claimed nucleic acid sequences; and the instant issue is whether the asserted utilities meet the three-pronged test for a patentable utility. Secondly, since the specification fails to disclose a specific, substantial utility or a well-established utility, the present claims do not satisfy the utility requirement of 35 U.S.C. '101. Merely citing case law on the utility requirement does not render a patentable utility for the present invention. While "anything under the sun that is made by man" is patentable, it does not necessarily mean the present invention is patentable. In fact, the present invention is not patentable due to lack of a patentable utility. Furthermore, while the FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws, and the requirement for the utility of the claimed invention is different from the FDA standard for drug approval, 35 U.S.C. '101 does require a specific, substantial, and credible utility, or well-established utility for an invention. Such a utility has to be a "real world " context of use which does not require significant further research. Appellant confuses this requirement with the "further research and development" needed in pharmaceutical composition and drug development. In other words, a patentable utility has to be clearly identified or immediately apparent in the specification, whereas some "further research and development" is permitted in drug development. For example, determining optimal dosages or drug tolerance in human is further research and development, which is acceptable under 35 USC 101 because it is not significant. On

the other hand, determining a specific disease to be treated by a drug constitutes significant further research and development, which is not acceptable under 35 U.S.C. '101. In the instant case, the specification fails to disclose the biological functions, physiological significance, or any specific and substantial utility of the claimed molecules. Without such information, one in the skilled art cannot use the claimed invention in a meaningful manner. See Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." It is further noted that the instant application was filed November 16, 2000. No evidence on the specific biological functions or physiological significance of the molecules of the present invention has ever been brought forth in an appropriate form during the prosecution history. This supports the Examiner's position that significant further research or undue experimentation is required to identify such information.

Appellants' assert on pages 11-12 of the brief that only one utility is needed to meet the requirements of 35 U.S.C. § 101, and that the present nucleotide sequence has a specific utility in determining the genomic structure of the corresponding human chromosome. Appellants further present Exhibit M, which shows the result of a blast (sequence alignment) analysis using SEQ ID NO: 1 of the present invention when compared to the identified human genomic sequence, and which indicates that the sequence of the present invention is encoded by 9 exons spread non-contiguously along a region of human chromosome 12, at approximately 12q21.

Appellants' arguments have been fully considered but are not deemed to be persuasive, because such a utility is considered a research use only designed to identify a particular function of the claimed sequences and is not a specific or substantial utility, i.e., is not a use of the invention. See, e.g., Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein such a research use was not considered a "substantial utility." Such a use of the polynucleotide sequences in gene mapping does not represent a specific and substantial utility. The exhibit and the publication cited by the Appellant merely show that the significance of expressed sequences in the structural analysis of genomic data; they do not show that the present polynucleotide sequences have a patentable utility.

On page 13, Appellants argue that the Examiner has used Skolnick et al as evidence that one cannot assign function to a protein based on overall structure or domain, however, Skolnick et al also states that structural information is likely to play an important role in high-throughput function assignments. Appellants submit that the sequences of the instant invention are essentially identical to protein recognized by those skill in the art to be a CD protein, similar to CD82 and CD63. Appellants also assert that the PTO has repeatedly attempted to use spurious articles to deny the utility of nucleic acid sequences based on a small number of publications that call into doubt prediction of protein function from homology information and the usefulness of bioinformatics predictions. Appellants agree that there is not 100% consensus within the scientific community regarding prediction of protein function from homology information, and further agree that prediction of protein function from homology

information is not 100% accurate. However, Appellants argue that the lack of 100% consensus on prediction of protein function from homology information is irrelevant to the question of whether the claimed nucleic acid sequence has a substantial and specific utility, and that 100% accuracy of prediction of protein function from homology information is not the standard for patentability under 35 U.S.C. § 101. Appellants point out that the legal test for utility simply involves an assessment of whether those skilled in the art would find any of the utilities described for the invention to be believable, and that the overwhelming majority of those of skill in the relevant art would believe prediction of protein function from homology information. Appellants also point out that the usefulness of bioinformatics predictions are powerful and useful tools, as evidenced by the extensive number of journal articles which support Appellants' assertion that the overwhelming majority of those of skill in the art place a high value on prediction of protein function from homology information and the usefulness of bioinformatics predictions, and would thus believe that Appellants' sequence is a CD-like protein similar to CD82 and CD63. Appellants further argue that the asserted utility for the described sequences is credible, and that according to the Examination Guidelines for the Utility Requirement, if the applicant has asserted that the claimed invention is useful for any particular purpose (i.e., it has a specific and substantial utility), and the assertion would be considered credible by a person of ordinary skill in the art, and the Examiner should not impose a rejection based on lack of utility.

These arguments have been fully considered but are not deemed persuasive. First, although the Skolnick et al reference indicates that structural information may play

an important role in high-throughput function assignments, in the instant case one of skill in the art would not predict that a protein that shares only 15% or 24% to another protein would retain the same activity. Second, as discussed above, while the protein of SEQ ID NO: 2 of the instant invention may have a high degree of identity to a protein identified in the art as CD63- like protein, the protein of SEQ ID NO: 2 of the instant invention is only 15.3% identical to human CD63 itself and 24.3% to human CD82; and it is therefore divergent from these proteins 84.7% and 74.7%, respectively. It is credible that the proteins of the instant invention are similar to CD63 and are probably in the CD membrane family, but given the high level of amino acid divergence, do not necessarily bind same ligands as CD63 or have the same activities. Therefore, similarity to CD proteins does not necessarily yield a specific and substantial utility and the credibility for the similarity is not questioned. Second, the issue is not that one of ordinary skill in the art would not find the uses for the nucleic acids or encoded protein believable or credible, it is that there is no specific or substantial uses asserted for the nucleic acids or encoded protein. A number of general uses are listed, for example on page 15, lines 18-30, which include the generation of antibodies, reagents in diagnostic assays, identification of other cellular gene products related to the protein, as reagents in assays for screening for compounds that can be pharmaceutical reagents useful in therapeutic treatment of mental, biological or medical disorders. Utilities that would appear to be more specific and substantial are implied by the statement on page 15, lines 6-15 of the specification, which discloses that the claimed sequences share structural similarity to CD37 and CD82 and display four transmembrane regions as

been seen by similar proteins. However, the different members of the CD family have different activities, and therefore, there is no unequivocal specific or substantial assertion.

Finally, at pages 14-15 of the Brief, Appellants challenge the legality of the Patent Examination Utility Guidelines and the validity of issued US patents. The Examiner has no authority to comment on the legality of the Guidelines and the validity of US Patents.

For the above reasons, it is believed that the rejections should be sustained. Appellants' arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the prima facie case of lack of utility and it is believed that the rejections should be sustained.

B. Are Claims 1-8 Unusable Due to a lack of Patentable Utility?

As Appellants indicate at page 15 of the Brief, a rejection under U.S.C. § 112, first paragraph, may be affirmed on the same basis as a lack of utility rejection under 35 U.S.C. § 101.

Therefore, for reasons set forth above, Appellant's arguments and exhibits have been fully and carefully considered, but are not considered sufficient to rebut the prima facie case of lack of utility. For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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July 8, 2004

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